SUPERFUND Fax:517-335-4887 Jul 24 2001 8:40 P.01

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

ENVIRONMENTAL RESPONSE DIVISION

FAX COVER SHEET

Date Sent: 7/24/01 To Machine # 312 886 4071

Time Sent: _____ From Machine # 517-335-4887

PLEASE DELIVER THE FOLLOWING PAGES TO:

Name: Tom Short

Company/Division: _____

Phone: _____

SENT FROM:

Name: Ken Gustad

Section/Division: _____

Phone: _____

TOTAL NUMBER OF PAGES (INCLUDING THIS COVER SHEET): 8

COMMENTS: KRSG Risk Assessment propaganda. This will apparently appear in Today's Kalamazoo Gazette.

IF ALL PAGES ARE NOT RECEIVED, PLEASE CALL:

Name: _____

Phone: _____

DEQ-143 (Rev.10/95)
PRINTED UNDER THE AUTHORITY OF ACT 451,1994 AS AMENDED

Perspective & Summary

of the

Human Health Risk Assessment

for the

Allied Paper, Inc./Portage Creek/Kalamazoo River

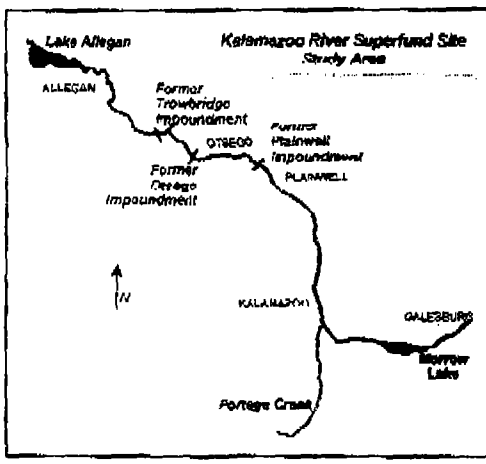
Superfund Site

Prepared by
Kalamazoo River Study Group

July 2001

Human Health Risk Assessment – Perspective and Summary

Polychlorinated biphenyls, better known as PCBs, were used in a number of industrial processes and commercial products until the late 1970s. They are the primary "constituent of concern" at the Kalamazoo River Superfund Site, and extensive studies to determine the nature and extent of their presence have been conducted over the past decade. This "Perspective and Summary" presents a brief description of the findings of a comprehensive human health risk assessment (HHRA) for the Kalamazoo River that was completed in June 2001.



The Kalamazoo River Superfund Site is located in southwest Michigan. The section of the river shown to the left, from Morrow Lake to Lake Allegan, is under investigation due to the presence of PCBs. This area is the focus of the comprehensive human health risk assessment conducted by Cambridge Environmental, Inc.

Background

When PCBs are detected at a site, it is often necessary to conduct a HHRA to evaluate concerns about possible human health effects. The Michigan Department of Environmental Quality (MDEQ) started this process by conducting a "screening-level" risk assessment in 2000 for the Kalamazoo River between Morrow Lake and Lake Michigan. This screening-level risk assessment (MDEQ, 2000) evaluated hypothetical populations and used the average and highest detected levels of PCBs to estimate the risks related to extreme cases of exposure. While such methods tend to substantially overestimate potential exposures to the constituents of concern, they can be used to reveal whether potential risks exist that should be evaluated further. If a screening-level assessment shows that estimated levels of exposure are within an acceptable range, one can conclude that the chemicals found at the site do not pose an unacceptable risk. If, however, estimated levels of exposure are above acceptable screening levels, then a more detailed study is needed to determine whether the estimated risks are due to actual site conditions or due to the conservative nature of the screening-level assessment.

What is a Human Health Risk Assessment?

A Human Health Risk Assessment is one of the tools used to determine the most appropriate cleanup action for a site. It presents estimates of current and possible future risks to health if no measures were taken to clean up the site. Risk assessments are generally carried out in four steps:

1. Data Collection & Evaluation – What chemicals exist at the site and where?
2. Exposure Assessment – To what extent could people come in contact with the chemicals?
3. Toxicity Assessment – What are the potential human health effects?
4. Risk Characterization – What are the risks due to various kinds of exposure? What kinds of exposure are not of concern?

The Need for This Study

The MDEQ screening-level risk assessment indicated the potential for unacceptable risks as a result of certain types of exposure to PCBs on the Kalamazoo River; therefore, a more detailed quantitative analysis was called for based on site-

specific data and more realistic assumptions that take into account local fishing behavior, land use, and the various important uncertainties in calculating risk. The Kalamazoo River Study Group, a group of current or former owners of some of the paper recycling facilities that existed in the Kalamazoo River watershed, retained Cambridge Environmental, Inc. (Cambridge) to perform the necessary quantitative HHRA for the Kalamazoo River Superfund Site (Cambridge, 2001). This quantitative assessment focused on the area of the river between Morrow Lake and the Lake Allegan Dam.

There are a number of uncertainties inherent in any risk assessment. In this case, there is also an overarching uncertainty associated with the assumption that low levels of PCBs can cause cancer and other health problems in humans. In fact, the International Agency for Research on Cancer (IARC) does not currently list PCBs among the 87 substances (including arsenic and asbestos), mixtures (such as alcoholic beverages or tobacco smoke), or exposure circumstances (such as aluminum production) known to cause cancer in humans (IARC, 2001). Similar uncertainty exists in the consideration of non-cancer health effects, which have not been reliably or consistently linked to low levels of PCB exposure. The MDEQ did not incorporate these uncertainties into its screening level assessment, whereas Cambridge's quantitative HHRA does factor in the variability and uncertainty in PCB toxicity values.

Overview of the New Quantitative HHRA

Cambridge's quantitative HHRA supplements MDEQ's screening-level assessment by incorporating more detailed analyses based on site-specific data (compared to data drawn from literature), complete fish sampling and analysis data from 1993, 1997, and 1999 (versus using just average and maximum values from 1993 and 1997), and information gathered in a particularly robust state-sponsored survey of Kalamazoo River anglers (as opposed to evaluating a hypothetical population). A number of exposure pathways – which are ways that a person could come in contact with any PCBs in and around the river – were evaluated, including exposure to PCBs as a result of eating Kalamazoo River fish; through contact with the exposed sediment in the state-owned former Plainwell, Otsego, and Trowbridge impoundments during recreational activities; and other pathways such as exposure during swimming or through inhalation of PCBs.

Fish consumption is the only significant PCB exposure pathway on the Kalamazoo River. Swimming, boating, and wading are enjoyable and safe.

An important distinction between Cambridge's HHRA and MDEQ's assessment is that Cambridge's evaluation of estimated risk to anglers consuming fish from the river accounts for variability among individuals in the potentially exposed populations as well as the uncertainties inherent in any measurement. The estimates of potential risk presented in the quantitative HHRA for anglers correspond, as closely as possible, to the actual situation along the Kalamazoo River and to the populations who may be exposed to PCBs.

In addition, Cambridge did not evaluate exposure to the exposed sediments in the state-owned former impoundments for a resident like MDEQ did – since the land is all state-owned, residential development is unlikely. Instead, Cambridge performed screening-level evaluations of potential exposure to PCBs due to recreational activity on the former impoundments. While the recreational scenarios Cambridge developed are more realistic than the MDEQ's residential scenario, they are still very conservative and consider potentially highly-exposed populations.

Primary Findings of Cambridge's HHRA

Results of Cambridge's quantitative HHRA reveal that eating fish caught in the Kalamazoo River is the only activity that could potentially lead to unacceptable risks that are relevant to remedial decision-making at this site. In order to estimate the potential risk for anglers who eat the fish they catch from the river, a number of factors were taken into account. They include:

- Concentrations of PCBs in fish, which are reported in the draft *Remedial Investigation Report* (BBL, 2000a) and the *Supplement to the Kalamazoo River RI/FS* (BBL, 2000b);
- Number of meals of Kalamazoo River fish eaten by anglers per year;
- Size of fish meals eaten;
- Number of years that anglers will catch and consume fish from the river;
- Species of fish consumed – carp tend to accumulate higher levels of PCBs than fish popular among Kalamazoo River anglers like catfish, panfish, and bass;
- Amount of PCB loss due to cooking methods; and
- Buildup of PCBs in anglers over time.

What level of risk is acceptable?

The United States Environmental Protection Agency (USEPA) and the MDEQ have both established targets for acceptable levels of excess cancer risk. In addition, non-cancer health effects are evaluated by comparing estimated doses of PCBs to the protective acceptable dose set by the Michigan Environmental Science Board.

- USEPA – acceptable range of risk is from less than 1 in 1,000,000 up to 1 in 10,000. This corresponds to a chance of between 1 in 10,000 and 1 in 1,000,000 that the exposure may cause cancer.
- MDEQ – acceptable risk limit is 1 in 100,000. This corresponds to a 1 in 100,000 chance that the exposure may cause cancer.
- Michigan Environmental Science Board Health Protective Value – acceptable dose of 0.05 micrograms of PCBs per kilogram of body weight per day (µg/kg per day). Below this dose, adverse health effects would not be expected.

Some of these factors were measured directly (such as PCB concentrations in fish), while most of the information used to estimate risk was gathered through interviews with Kalamazoo River anglers. The Kalamazoo River Angler Survey, conducted by the Michigan Department of Community Health (ATSDR, 2000) contains the results of more than 900 interviews conducted with anglers in order to acquire information on fishing activities and fish-eating habits, and provides an unusually robust source of data not generally available in a risk assessment.

Both present and future risks to the current population of anglers who catch and eat fish from the river were evaluated in order to support decisions about how the river will be managed in the future. An analysis of the angler survey and the levels of PCBs in fish reveals a range of both estimated doses of PCBs (i.e., amount of fish eaten) and potential

risks for anglers. These ranges exist both because people differ in their habits and because there are unavoidable uncertainties in any risk assessment.

Both cancer and non-cancer health effects are considered when evaluating potential exposure to PCBs. While estimates of cancer risk are based on *lifetime* average daily doses, non-cancer risks are based on average daily doses (the exposure is averaged over the period when people actually eat fish, rather than over an entire lifetime). During the period of exposure, any estimated daily dose may be higher than the lifetime average, but some people are exposed to that daily dose for a period as short as one year (the assumed minimum period for eating fish from the Kalamazoo River), or it may extend out over a lifetime.

Estimated health risks from eating Kalamazoo River fish, based on a full probabilistic analysis incorporating the variability and uncertainty of both doses and PCB toxicity values, are summarized in the table below.

Summary of Estimated Risks Associated with Consumption of Kalamazoo River Fish

Level of Estimated Cancer Risk	Population-Wide Estimated Cancer Risk	Level of Estimated Non Cancer Risk	Doses as Compared to the Health Protective Value (HPV) of 0.05 µg/kg per day
1.7 (or less) chance in 100,000 with 90% probability	90% chance there will be less than 2.2 additional cases of cancer ever in the entire fish-eating population	Hazard Index = 0.81 at 90th percentile *(values less than 1.0 indicate there is no non-cancer risk)*	• 92% chance that the *lifetime average dose* will be below HPV • Estimated *median lifetime average dose* is twenty times less than the HPV • 49% chance the *average daily dose* will be below HPV • Estimated *median average daily dose* is equal to the HPV

When evaluating these results, several factors should be kept in mind, including:

- PCB levels in fish are declining, on average, about 5% every year. Over the past 20 years, natural recovery processes, such as the mixing and covering of PCB-containing sediment with progressively cleaner sediments, have been contributing to measurable decreases in the amount of PCBs available in the top layer of Kalamazoo River sediment. Lower levels of PCBs in surface sediments means lower levels of PCBs available to fish. This decline over time will continue absent any active clean-up at the site.

- When evaluating non-cancer health risks, the Michigan Environmental Science Board's Health Protective Value (HPV), which sets an acceptable dose of 0.05 µg/kg per day (see text box on page 3), is considered to be overly protective for the majority of the population. That is, it is designed to protect the most sensitive members of the population. Regardless, it is estimated that there is a less than 8% chance for *any* random fish-eating angler to be exposed to a dose higher than the Health Protective Value.

- The plausible high-end hazard index for an individual who eats fish is 0.81 (at the 90th percentile). Hazard index values less than 1.0 indicate that there is no significant risk of non-cancer health effects.

- The population of fish-eating anglers is relatively small. Fewer than 7,000 people are estimated to consume Kalamazoo River fish during any given season.

- The number of additional PCB-related cancers calculated for all the people who ever eat fish from the Kalamazoo River over the entire future (assuming a full probabilistic analysis) is less than 0.11 (at the median estimate), and there is a 90% certainty that for as long as people in the community catch and eat fish from the river, no matter how long that may actually turn out to be (20 years, 200 years, even forever), the total effect would be less than 2.2 additional cases of cancer throughout the entire fish-eating population. It is, however, most likely that there will be no extra cases of cancer across the population as a result of eating fish from the Kalamazoo River. Heeding the consumption advisories along with the fish filleting and cooking guidelines issued by the Michigan Department of Community Health are ways anglers can reduce exposure and still enjoy fishing on the Kalamazoo.

Overall Conclusions

Although there are several ways people could come into contact with PCBs along the Kalamazoo River, only one of these exposure pathways – eating fish caught in the river – has the potential to lead to unacceptable health risks that are relevant to remedial decision-making for the river. However, these risks are low, and when considering the total effect due to PCB exposure among all the people who ever eat fish from the Kalamazoo River (for another 20 years, 200 years, or even forever), it is unlikely (74% probability) that there will be any additional cases of cancer throughout the entire fish-eating population. In addition, the results of the hazard index analysis – designed to determine the potential risk for non cancer health effects – reveal that the plausible high-end hazard index is 0.81 (at the 90th percentile). Any hazard index less than 1.0 indicates that there is no significant risk of non-cancer health effects. Other potential risks, such as inhaling PCBs coming off the soils in the three former impoundments or from the river water, are negligible, as are the risks faced by swimmers and boaters on the river. Any efforts to reduce risks related to PCB exposure along the Kalamazoo River should therefore focus on reducing levels of PCBs in those species of fish used for food, and maintaining awareness of potential PCB exposure through the use of fish consumption advisories and other public education tools.

About Cambridge Environmental, Inc.

Cambridge Environmental specializes in quantitative assessment of risks to health and the environment posed by chemical, physical, and microbiological agents. They apply regulatory risk assessment techniques, but also implement more rigorous methods when the regulatory approaches are inappropriate or inadequate. They construct models based on first principles of science and engineering, support them by experimental data, and address uncertainties. Their assessments are guided by local concerns, guidelines, policies, and precedents.

See www.CambridgeEnvironmental.com for more information on Cambridge Environmental, Inc.

The primary authors of Cambridge's quantitative HHRA for the Kalamazoo River are listed below.

Laura Green, Ph.D., D.A.B.T.
Senior Scientist and President

Dr. Green has performed original research, published, and consulted in the areas of chemical carcinogenesis, toxicology and pharmacology, food chemistry, analytical chemistry, risk assessment, and regulatory policy. Prior to founding Cambridge Environmental, Dr. Green was Senior Vice President at Meta Systems Inc. and the founder and director of Meta System's Environmental Health and Toxicology group. She also served as Research Director of the Scientific Conflict Mapping Project at the Harvard University School of Public Health.

Dr. Green holds a B.A. from the Department of Chemistry at Wellesley College (1975) and a Ph.D. from the former Department of Nutrition and Food Science (currently the Division of Toxicology) at the Massachusetts Institute of Technology (1981). She is a diplomate of the American Board of Toxicology (D.A.B.T.).

Edmund Crouch, Ph.D.
Senior Scientist

Dr. Crouch has published widely in the areas of environmental quality, risk assessment, and presentation and analysis of uncertainties. He has co-authored a major text in risk assessment, *Risk/Benefit Analysis*. Dr. Crouch serves as an expert advisor to various local and national agencies concerned with public health and the environment, and has served on two National Academy of Science Committees. He has designed Monte Carlo simulations for purposes of fully characterizing uncertainties and variabilities inherent in health risk assessment.

Dr. Crouch holds a B.A. in Natural Sciences (Theoretical Physics) (1972) and a Ph.D. in High Energy Physics (1975), both from Cambridge University, United Kingdom.

Michael Ames, Sc.D.
Associate Engineer

Dr. Ames has conducted original research in the areas of sampling and elemental analysis of environmental materials by Instrumental Neutron Activation Analysis (INAA), and source identification and apportionment by receptor modeling. His current work includes health risk assessments of atmospheric particulate matter and of contaminants in ground water and river sediments.

Dr. Ames holds a B.S. (1984), an M.S. (1986), and an Sc.D. (1995) in Nuclear Engineering from the Massachusetts Institute of Technology.

References

Agency for Toxic Substances and Disease Research (ATSDR). 2000. *Kalamazoo River Angler Survey and Biological Testing Study*, submitted to the Michigan Department of Community Health (Atlanta, GA: May 2000).

Blasland, Bouck and Lee, Inc. (BBL). 2000a. *Allied Paper, Inc./Portage Creek/Kalamazoo River Superfund Site – Remedial Investigation Report – Phase I* (Syracuse, NY: October 30, 2000).

BBL. 2000b. *Allied Paper, Inc./Portage Creek/Kalamazoo River Superfund Site – Supplement to the Kalamazoo River RI/FS – Phase I* (Syracuse. NY: October 30, 2000).

Cambridge Environmental, Inc. (Cambridge). 2001. *A Quantitative Health Risk Assessment for the Kalamazoo River PCB Site* (Cambridge, MA: June 1, 2001).

International Agency for Research on Cancer (IARC). 2001. *Overall Evaluations of Carcinogenicity to Humans, Group 1: Carcinogenic to humans*, available at: http://193.51.164.11/monoeval/crthgr01.html.

Michigan Department of Environmental Quality (MDEQ). 2000. *Human Health Risk Assessment – Allied Paper, Inc./Portage Creek/Kalamazoo River Superfund Site*. MDEQ Environmental Response Division (Lansing, MI: August 18, 2000).